

REMARKS

This document is filed in reply to the Office Action dated May 7, 2010 ("Office Action").

Applicants have amended claim 1 to promote clarity. Support for the amendment can be found in Figure 1 of the Specification and also in claim 4, now canceled. Cancellation of claim 4 has necessitated dependency changes to claims 8 and 9. Claims 6, 12, and 14-19 are also amended for clarity. Applicants have also amended claim 3 to more properly recite means plus function language and amended claim 11 to correct a typographical error. No new matter has been introduced by the above amendments.

Note that claims 12-19 were previously withdrawn for covering a non-elected invention.

Upon entry of the amendments, claims 1, 3, and 5-23 will be pending. Among them, claims 1, 3, 5-11, and 20-23 are under examination. Applicants respectfully request that the application be reconsidered in view of the following remarks.

Objection to Claim

Claim 11 is objected to for a typographical error. The claim has been amended to overcome this objection.

Rejections of claims 1, 3-4, 7, 9-11, and 21-23 under 35 U.S.C. § 103

Claims 1, 3-4, 7, 9-11, and 21-23 are rejected for obviousness over US Patent No. 5128048 to Stewart *et al.* ("Stewart") in view of Nishimura, European Patent Application 0591980A2 ("Nishimura"). See the Office Action, page 2, item 5. As claim 4 has been canceled, Applicants will only discuss the other rejected claims. Independent claim 1 is addressed first.

A

Claim 1 as currently amended is drawn to a device for separating blood into blood components.

The device includes several structural elements (as numbered in Figure 1 of the Specification), all of which are recited in amended claim 1: a collecting container (2) for receiving whole blood, a first satellite container (4) connected to the collecting container through a leukocyte filter (22) for receiving from the collecting container a leukocyte depleted first blood component, a second satellite container (6) connected with the collecting container for receiving from the collecting container a leukocyte depleted second blood component, by-pass conduit means and conduit means (16a, 16b, 16c, 28a, 28b, 34) to connect the containers and leukocyte filter, and flow control means (36, 38, 40, 42) to direct flow of leukocyte depleted first and second blood components through the conduit means. The flow control means and conduit means are arranged such that a whole blood (WB) sample is processed by the device in two steps using the leukocyte filter twice.

In the first step, the first satellite container receives from the collecting container a leukocyte depleted platelet rich plasma component (PRP) and in the second step, the second satellite container receives from the collecting container a leukocyte depleted packed red cells component (PRC).

The Examiner rejects claim 1 on two grounds. Applicants respectfully traverse each of them below.

I

The Examiner rejects claim 1 on the ground that it would have been obvious to a skilled artisan to replace the leukocyte filter in the Stewart device with the Nishimura leukocyte filter to arrive at the device of claim 1. See the Office Action, page 4, top paragraph. Applicants disagree.

Stewart and Nishimura, the two references relied on by the Examiner teach a blood separating device and a leukocyte filter, respectively.

Stewart teaches that PRP is received from a collecting container via a by-pass tube, thereby circumventing a leukocyte filter (see column 6, lines 14-18), and further teaches that leukocyte free PRC is received via a transfer path passing through the leukocyte filter (see column 6, lines 19-23). In other words, Stewart teaches separation

of whole blood into two components using a leukocyte filter only once. Nowhere is it suggested in Stewart using a leukocyte filter twice to separate whole blood into two components as required by claim 1. Nishimura, the other reference, does not cure this deficiency.

Indeed, as correctly pointed out by the Examiner, Nishimura merely teaches a leukocyte filter that allows platelets to pass therethrough. See the Office Action, pages 3-4, bridging paragraph. It does not suggest inclusion of flow control means that would remedy the deficiency of the Stewart device.

In sum, the Examiner errs in concluding claim 1 would have been obvious over Stewart and Nishimura.

II

The Examiner rejects claim 1 on a second ground, stating that “[m]aterials such as blood, PRP, PRC, [and] WB ... [should] not [be] given patentable weight in the [claim].” See the Office Action, page 3, first paragraph.

Applicants submit that terms such as WB, PRP, and PRC are recited in claim 1 to facilitate understanding of the claimed device for use in separating blood into blood components. The patentability of the device of claim 1 resides at least in the arrangement of its structural elements and does not need to reside in WB, PRP, or PRC stored in or pushed through the structural elements.¹ See the “twice” feature discussed above at page 11, first paragraph and page 12, first paragraph.

III

In view of the remarks set forth in Subparts I and II above, Applicants submit that claim 1 is nonobvious over Stewart in view of Nishimura. So are claims 3, 7, and 9-11, all of which depend from claim 1.

¹ Recitations such as WB, PRP, and PRC in claim 1 should be given patentable weight in view of the preamble, which reads “[a] device for separating blood into blood components [such as PRP and PRC]”. Applicants previously presented arguments to this effect based on guidelines provided in MPEP 2111.02. See pages 10-11 of the last response, yet the Examiner failed to address those arguments.

B

Like claim 1, claim 21, the other rejected independent claim, is drawn to a device that uses a single leukocyte filter twice to separate blood into blood components. The device includes a collecting container, a single leukocyte filter, satellite containers, conduits (e.g. a by-pass conduit), and valves, wherein one valve provides fluid flow from a second satellite container into the collecting container only through the by-pass conduit. These structural elements are arranged so that the leukocyte filter is used twice.

Claim 21 is rejected by the Examiner on the same two grounds as claim 1, each of which are addressed separately below:

First, the Examiner contends that it would have been obvious to replace the leukocyte filter in the Stewart device with the Nishimura leukocyte filter to arrive at the device of claim 21. See the Office Action, page 6, third paragraph. Applicants disagree.

To summarize the previous remarks presented in Part A, Subpart I above, Stewart teaches separation of whole blood into two components using a leukocyte filter only once. Nowhere is it suggested in Stewart using a leukocyte filter twice to separate whole blood into two components as required by claim 21. This deficiency is not cured by Nishimura.

Applicants therefore submit that the Examiner errs in concluding claim 21 would have been obvious over Stewart and Nishimura.

Second, the Examiner rejects claim 21 on a second ground, stating that “[m]aterials such as blood, PRP, PRC, [and] WB ... [should] not [be] given patentable weight in the [claim].” See the Office Action, page 6, top paragraph.

The remarks set forth in Part A, Subpart II above for claim 1 are also relevant to claim 21. Applicants submit that the patentability of the device of claim 21 resides at least in the arrangement of its structural elements and does not need to reside in WB, PRP, or PRC stored in or pushed through the structural elements.

In view of the remarks set forth above, Applicants submit that claim 21 is nonobvious over Stewart in view of Nishimura. So are claims 22 and 23 which depend from claim 21.

C

For a complete record, Applicants now address the specific grounds raised by the Examiner for rejection of claims 3, 7, 9-11, and 22- 23.

The Examiner alleges that further teachings of Stewart render the claims at issue obvious in view of the teachings of Stewart and Nishimura discussed above. For claim 3, see the Office Action page 4, second paragraph; for claims 7, and 9-11, see page 5; for claim 22, see pages 6-7, bridging paragraph; and for claim 23 see page 7, second paragraph. None of the teachings pointed out by the Examiner cures the deficiency of Stewart, as pointed out in Parts A and B above. More specifically, these teachings do not suggest the “twice” feature of the claimed device. It follows that none of these claims is rendered obvious by a combination of Stewart and Nishimura in any way.

The Examiner also rejects claim 3 on a specific ground, contending improper use of means plus function claim language. See the Office Action, page 4, second paragraph.

Claim 3 is directed to a device for separating blood into components using a leukocyte filter twice, containing flow control means configured to achieve said separation.

This claim has been amended to recite “said flow control means is configured for sequentially (a) allowing ...”. The amendment has made it clear that the flow control means are arranged so as to operate in a specific manner. In other words, the operation of the flow control means is a structural feature of, not an intended use for, the device of claim 3.

In any event, the device of claim 3 requires the “twice” feature as discussed above.

Rejections of claims 5, 6, and 20 under 35 U.S.C. § 103

Claims 5, 6, and 20, all directly or indirectly depending from claim 1, are rejected over Stewart in view of Nishimura and WO 03/063930 by Corbin *et al.* (“Corbin”). See the Office Action, page 7, item 6.

Corbin merely teaches an optical sensor for detecting color of blood components. Thus this reference, like Nishimura, does not rectify the deficiency of the Stewart device

discussed above. It follows that claims 5-6 and 20 are nonobvious over the three cited references.

Rejection of claim 8 under 35 U.S.C. § 103

The Examiner rejects claim 8 for obviousness over Stewart in view of Nishimura and US Patent No. 7264068 to Bischof *et al.* ("Bischof"). See the Office Action, page 8, item 7.

Bischof teaches a one-way valve provided in a by-pass conduit. Again, this reference does not rectify the deficiency of the Stewart device in view of Nishimura. Thus, claim 8 is patentable over Stewart in view of Nishimura and Bischof.

CONCLUSION

Based on the remarks presented above, Applicants submit that claims 1, 3, 5-11, and 20-23 are nonobvious over Stewart and Nishimura. Therefore, Applicants respectfully request withdrawal of the rejection.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment.

In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed.

Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

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Page : 16 of 16

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No fee is believed due. Please apply any other charges or credits to Deposit
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Respectfully submitted,

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